

**REMARKS****Status of the Claims**

Claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115 and 117-130 are pending in the present application. Claims 53 and 70 have been amended to correct obvious typographical errors. Newly added claims 129 and 130 are based upon claim 19, but each of claims 129 and 130 emphasizes what is already claimed and intended by the remaining claims. More specifically, claim 129 emphasizes an orally or mucosally pharmacologically effective amount of the active ingredient [e.g. glycosaminoglycan/hyaluronic acid [hereinafter HA]] and claim 130 expressly recites that it is the orally or mucosally administered glycosaminoglycan that produces a pharmacological effect.

**Claim Rejections - 35 U.S.C. §103**

The Examiner has rejected claims 7, 11, 12, 14, 19, 22, 23, 36, 37, 41, 42, 46-48, 51, 53, 54, 59, 66, 69, 70, 72-90, 91-94, 112, 113, 114, 115 and 117-128 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,736,024 to Della Valle et al. in view of U.S. Patent No. 4,141,973 to Balazs. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

**The Present Invention**

Each of the present independent claims require that the active ingredient is either glycosaminoglycan or, for instance, HA. Further the claimed carrier clearly excludes HA since the claimed active ingredient is either glycosaminoglycan or HA and the present specification

and claims clearly require separate active ingredients and carriers. Further, the present inventors utilize "carrier" in the conventional sense such that the "carrier" is not active. Such a conventional definition excludes active carriers such as HA. That is, the present inventors do not assign a nonconventional definition to the term "carrier."

Further, the type of carrier required by claims 19, 22, 23, 70, 73, 92, 94, 112, 117, 119, 128, 129 and 130 also excludes HA as the carrier. For instance, in many of these claims, the carrier is a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement.

#### *Distinctions Between The Present Invention and The Prior Art*

U.S. Patent No. 4,736,024 to Della Valle et al. [Della Valle] recites pharmaceutical preparations for topical administration containing a pharmacologically active substance together with HA. Clearly, HA is not the active ingredient in the Della Valle compositions. Rather, Della Valle expressly teaches that HA is the vehicle or carrier to be used with "one or more pharmacologically active substances." See, for instance, abstract and col. 1, lines 11-25.

Indeed, HA is never intended to be used as an active ingredient in Della Valle. See col. 5, lines 55-60. Moreover, HA is specifically defined as the vehicle or carrier in Della Valle. Clearly, HA is only desirable as a carrier in Della Valle. Obviously, one of ordinary skill in the art would recognize that the definition of vehicle in Della Valle is unique to Della Valle since vehicles/carriers in the art are generally known to be inert/not active.

The desirable properties of HA as a carrier are set forth, for instance, in col. 2, lines 44-51 and 65 - col. 3, line 9 of Della Valle. Clearly, HA is intentionally not included in the definition of an active ingredient in Della Valle. As the Examiner points out, Della Valle knew that ultrapure HA [eg. of Balazs] was active. However, Della Valle intended HA's use as a carrier for other active ingredients. This point is further emphasized in the definitions of "Component (1) -Pharmaceutical Substance," which begins at col. 3, line 16. In fact, HA is clearly limited to use as "Component (2) – Hyaluronic Acid Vehicle" beginning at col. 5, line 14. Della Valle then combines these mutually exclusive components beginning at col. 7, line 30. Also see the Della Valle examples.

Accordingly, Della Valle EXPRESSLY teaches away from the use of HA as an active ingredient as claimed in the present invention.

Balazs teaches **ultrapure HA** and the use thereof. In Balazs, the ultrapure HA is the active ingredient.

The Examiner relies upon the teachings at col. 5, lines 15-45, which recites Balazs, in order to provide motivation for combining the teachings of Della Valle and Balazs. But, the Examiner ignores the description which immediately follows, for instance, at col. 5, lines 56 – 60 of Della Valle, which states:

In contrast to this therapeutic use...in the present invention, hyaluronic acid or its molecular fractions are used as **vehicles** for administration of pharmacologically active substances for topical use.

The Examiner's reliance upon only a portion of the teachings of Della Valle with respect to Balazs clearly ignores the express "teaching away" by Della Valle. Contrary to the Examiner's position, there can be no motivation to combine the teachings of Della Valle in the manner

suggested. This is especially true since modifying the teachings of Della Valle in order to obtain the present invention is directly contrary to and destroys the teachings of Della Valle.

Accordingly, one of ordinary skill in the art upon reading the teachings of the Della Valle and Balazs – e.g. as contemplated by Della Valle – would not obtain the present invention. The Examiner's position is directly contrary to the teachings of Della Valle, since Della Valle states that in contrast to col. 5, lines 15-45 [relied on by the Examiner for motivation], one of ordinary skill in the art MUST go in a DIFFERENT direction. That is, HA should be used as a vehicle [carrier] and not as an active ingredient in his invention. Since Della Valle was aware of Balazs and teaches the opposite of what the Examiner suggests, there is no motivation for combining these references in the manner suggested and the rejection should be withdrawn.

Further, the Examiner concedes that the types of the claimed carriers are not disclosed in either Della Valle and Balazs. See last paragraph on page 6 of Office Action. The Examiner ignores that Balazs uses ultrapure for HA surgical uses. Certainly, such surgical uses of highly pure material can not suggest the claimed formulations including carriers such as a drink, a drink mix, a food, a candy, a mouthwash, a toothpaste, a gargle, a vaporizer liquid, a gum, a lozenge, an ingestable gel, an ingestable foam, an ingestable capsule, a tablet, an ingestable tablet, an ingestable dissolvable tablet, a suppository, and an ingestable nutritional supplement. The same logic applies to Della Valle.

In the first paragraph on page 4 of the Office Action, the Examiner states that "since the HA can be applied orally or nasally it would have been obvious to someone skilled in the art that HA is of at least food grade purity." Such a conclusion is without basis. One of ordinary skill in the art would immediately know that food grade purity HA is so impure that it would NEVER be

used for surgery and it would NEVER pass the test required by the cited prior art e.g. monkey eye test. Therefore, even if the references were combined in the manner suggested by the Examiner, the combination would not suggest the present invention since the present invention allows for impure HA [eg food or cosmetic grade] whereas Balazs clearly does not allow for such impure materials. Thus, the combination would not suggest the present invention e.g. see claims 23, 72, 73, 92, 94, wherein a suitable active ingredient must pass the claimed purity test to be within the scope of the invention, or claim 59, wherein a suitable active ingredient is non pure or low purity or food grade.

In summary, in the present invention, it is the glycosaminoglycan/hyaluronic acid, which is orally or mucosally administered as an active ingredient, that produces a pharmacological effect. In contrast, in Della Valle, it is the active ingredient and not the vehicle [HA] which is to produce the pharmacological effect. There is no motivation to delete the active ingredient of Della Valle so as to merely use the vehicle as the active ingredient. Such a conclusion is directly contrary to Balazs. Also, there is no motivation to use the Balazs ultrapure HA as an active ingredient in Della Valle since Della Valle was aware of Balazs and expressly decided not to use the ultrapure HA of Balazs as the active ingredient. On the contrary, Della Valle decided to use pure HA as a carrier together with other active ingredients. Such a composition does not suggest the claimed composition. Moreover, there is no suggestion to utilize non pure HA such as food grade HA in either reference. One of ordinary skill would never use low grade HA for surgery due to the impurities. Such a modification would destroy the teachings of the underlying references. Accordingly, the rejection should be withdrawn since the combination does not suggest the present invention.

Finally, rejoinder of the method claims is requested.

If the present amendment does not place the application into condition for allowance,  
then the Examiner is requested to contact the undersigned at 703-205-8000.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Marc S. Weiner, Reg. No. 32,181 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By

  
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